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(72) Inventor ARTHUR STEVE MESSORES

(54) PRODUCING A SURGICAL SUTURE

(71) We, ETHICON INC., a corporation organised under the laws of the State of New Jersey, United States of America, of Somerville, New Jersey, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The majority of surgical needles sold to hospitals are swaged needels because of the many practical advantages of the swaged needle-suture combination over the eyed needle. Swaged needles can be either drilled, i.e., having a cylindrical hole drilled in the blunt end of the needle, or channeled, e.g. constructed with a "U"-shaped channel at the blunt end which is closed around the suture during the swaging process. Countless nurse-hours are consumed in surgery in the proper care, resharpening, and re-sterilization of eyed needles. All of this expenditure of valuable time is avoided with the use of swaged-on needles. The time spent by the scrub nurse threading eyed needles at the operating table is also saved. No surgeon-time is lost as it may be in the accidental unthreading of eyed needles.

The use of swaged needles is advantageous to the patient as well as to the surgical team. Only one strand of suture material need be drawn through a tissue when a swaged-on needle is used. Tissue trauma is reduced markedly when contrasted with the amount of trauma caused by eyed needles pulling a double strand of suture through the tissue. Swaged needles are used only once and then discarded, guaranteeing consistent sharpness. Tissue trauma is even further reduced when doubled sutures are eliminated.

When uniting any of the many different types of suture material to a surgical needle, effort is made to match the size (diameter) of the suture with the size (wire diameter) of the needle. Unless otherwise indicated, the diameter of a suture is measured by the method described in the United States Pharmacopoeia Vol. XVIII, Page 943. Thus, a Size 4/0 suture (diameter 0.152 mm.—0.203 mm.; 6—8 mils) may be united with a needle characterised by an outside diameter of 22 mils and a drilled hole in the blunt end of 10.4 mils. A somewhat larger Size 3/0 suture (diameter 0.203 mm—0.254 mm.; 8—10 mils) would be united to a needle having a drilled hole in the blunt end that is 13 mils in diameter. Size 2/0 sutures (diameter 0.254 mm.—0.330 mm. or 10—13 mils) would be swaged to a needle characterized by an outside diameter of 26 mils having a drilled hole in the blunt end of 16 mils. A Size 0 suture (diameter 0.330 mm.—0.406 mm.; 13—16 mils) might be attached to a needle of an outside diameter (39 mils) and having a drilled hole in the blunt end of 19 mils.

The present invention solves a manufacturing problem that results from the many different types of suture materials that are attached to surgical needles.

One advantage of the present invention, therefore, is that the manufacture of swaged needle-suture combinations is facilitated since the same needle (same wire size and drill hole diameter) may be swaged to various suture materials. Prior to the present invention, a Size 4/0 monofilament suture could easily be swaged to a 22 mil. needle having a 10.4 mil. drilled hole, but a Size 4/0 braided or covered suture required a larger needle having a larger drilled hole or channel.

Another advantage facilitated by the present invention is that the end dimensions of the sutures to be attached to the needle may be so controlled that the "pull-out" value after swaging can be held within the advantageous range of 3 ounces and 26 ounces. The pull-out value may be defined as that force required to cause the suture to separate from the needle and the advantage of a pull-out value between 3 and 26 ounces, is described in our co-pending Application No. 25709/73 (Serial No. 1,428,559).

In accordance with the present invention we provide a method of preparing a suture

which comprises winding a strand of suture material onto a rack under tension, dipping a section, intended for eventual cutting, of the wound strand into a supply of binder material while under tension, removing the strand on the rack from the binder supply and air-drying the binder-coated strand before releasing it from the rack. The binder material is preferably a resin solution. The dried binding composition which coats and impregnates the braided suture stablizes the diameter to that achieved under tension. The binder material prevents "brooming" when the suture is cut and the diameter of the binder-coated end of the suture does not change even after the tension is relaxed.

The multifilament suture utilized in the present invention may be absorbable, e.g., a braided polyhydroxyacetic ester, a synthetic copolymer of L(-)lactide and glycolide; or non-absorbable, e.g., braided silk, nylon, cotton, linen or DACRON (registered Trade Mark).

The binder material that is used to coat the suture while it is retained under tension may be any non-toxic adhesive composition, either organic, inorganic or a hybrid. Suitable organic materials are such natural products as starch, dextrin, asphalt, animal and vegetable proteins, natural rubber, shellac; semi-synthetic products such as cellulose nitrate and the other cellulosics, polyamides derived from dimer acids, castor-oil based polyurethanes; such well-known synthetic resins as vinyl-type addition polymers, both resins and elastomers; polyvinyl acetate, polyvinyl alcohol, acrylics, unsaturated polyesters, butadiene/acrylonitrile, butadiene/styrene, neoprene, butyl rubber, polyisobutylene; and polymers formed by condensation and other step-wise mechanisms, i.e., epoxies, polyurethanes, polysulfide rubbers, and the reaction products of formaldehyde with phenol, resorcinol, urea, and melamine. Particularly preferred as bonding compositions are the epoxide resins.

The invention will become more readily apparent upon consideration of the following detailed description when taken in connection with the accompanying drawings wherein:

Figure 1 is a front elevation of apparatus useful in winding sutures under tension;

Figure 2 is a perspective view of a braided suture strand wound on a rack frame under tension;

Figure 3 is a front elevation, partly in section, which illustrates coating the braided suture strand while under tension on the frame with a resin solution;

Figure 4 illustrates the frame with the tensioned suture strand in place after the sizing step;

Figure 5 is an enlarged fragmentary view of the sized end of a braided suture.

The apparatus illustrated in Fig. 1 is designed to wind a strand of suture material, such as braided silk, on to an open rack under tension. It includes in part, a spindle 10 that supports a spool 11 of braided silk 12. The silk strand from the spool passes over a guide 14 and through a mechanical friction brake 15. The tension applied to the moving strand by the brake 15 may be adjusted by sliding a movable weight 16 along its supporting rod 17.

From the mechanical brake 15, small size strands (Size 3/0 and smaller) pass directly to the tensiometer as indicated by the dotted line in Fig. 1. Sutures that are larger in diameter than Size 3/0 (Size 2/0 and larger) pass from the mechanical brake 18 which may be adjusted by means of a rheostat 20 to increaseor decrease the tension applied to the moving strand. The tension applied to the moving strand is regulated by a tensiometer 22.

The tensioned strand is taken up on a rack 24 which is rotated about its vertical axis 26 by a motor (not shown). The rack as it rotates is interconnected with a screw 28 mounted for rotation in a lower bearing 30 and upper bearing 31. This screw engages the threads of a nut 32 that is integral with a bracket 34. The pitch of the screw and its angular velocity are such as to move the bracket and associated idler pullies 35 and 36 upwardly in the direction of the arrow, thereby winding the tensioned strand evenly upon the rack.

To complete the description of the tensioning apparatus, a cam-actuated dancer roll 38 moves vertically up and down between idler rollers 39 and 40 as indicated by the arrows. The dancer roll compensates for any change in the tension that would otherwise occur by reason of variation in the linear acceleration of the suture material as the rack rotates at a constant angular velocity.

After the braided strand has been wound evenly on the rack, the end is tied to stabilize the tension and the rack with the braided strand in place is removed from the tensioning apparatus and a binder resin is applied (Figs. 3, and 4). The rack 24 is immersed to a depth of about 1.5 inches in a container 42 of resin solution 43 for approximately 5 minutes as shown in Fig. 3 to assure penetration of the binding into the interstices of the braid. The rack is then removed from the container and air dried at room temperature. The extent of the resin coating thus applied to the braided strand is indicated by the dotted line Z—Z in Fig. 4.

The resin-coated sutures are then removed from the rack by cutting along the lines X—X and A—A of Fig. 4. The sutures so obtained have a length slightly less than the width of the rack and are tipped at one end

for a distance of about 0.75 inches. As best shown in Fig. 5, the resin-coated end 44 of the suture 12 is smaller in diameter than the remainder of the suture.

If it is desired to manufacture a double-armed suture, i.e., a suture having a needle attached to each end, the width of the rack 24 is adjusted appropriately and the sutures are removed from the rack by making a single cut along the line X—X.

The following Examples will serve to illustrate the invention.

EXAMPLE I

A Size 4/0 black braided silk strand characterized by an optically determined diameter of 7.8 mils is wound on a rack 19¼ inches in width under a tension of 0.6 pounds, using the apparatus illustrated in Fig. 1. One end of the rack is immersed in a container of xylol in the manner illustrated in Fig. 3 to remove from the braid any coating used during the braiding process. The rack is removed from the container and the xylol is permitted to evaporate from the braided silk at room temperature.

That end of the rack that has been treated with xylol is then immersed in a container of a resin solution as in Fig. 3 containing 18 per cent by weight of a linear saturated polyester polymer having a molecular weight in the range of 20,000—30,000 and characterized by a ring and ball softening point of 158°C. (VITEL PE—3912—A manufactured by Good Year Chemical Division of the Good Year Tire and Rubber Company, P.O. Box 2008, New Brunswick, New Jersey 08903; VITEL is a registered Trade Mark). The rack is immersed to a depth of about 1¼ inches for about 5 minutes.

The rack is removed from the resin solution and air dried at room temperature for a minimum of ½ hour. The sutures are then removed from the rack by cutting along the lines X—X and A—A. The sutures so obtained are approximately 18 inches in length and the resin-coated end measures about ½ to 1 inch. The diameter of the resin-coated end is 7.5 mils (determined optically).

EXAMPLE II

A Size 3/0 black braided silk strand characterized by an optically determined diameter of 9.9 mils is wound on a rack 19¼ inches in width under a tension of 0.9 pounds, using the apparatus illustrated in Fig. 1. One end of the rack is immersed in a container of xylol as illustrated in Fig. 3 to remove from the braid any coating used during the braiding process. The rack is removed from the container and the xylol is permitted to evaporate from the braided silk at room temperature.

The end of the rack that has been treated with xylol is then immersed in a container of a resin solution as described in Example I above.

The rack is removed from the resin solution and air dried at room temperature for a minimum of ½ hour. The sutures are then removed from the rack by cutting along the lines X—X and A—A. The sutures so obtained are approximately 18 inches in length and the resin-coated end measures about ½ to 1 inch. The diameter of the resin-coated end is 9.5 mils (determined optically).

EXAMPLE III

A Size 2/0 black braided silk strand characterized by an optically determined diameter of 12.9 mils in wound on a rack 19¼ inches in width under a tension of 1.4 pounds, using the apparatus illustrated in Fig. 1. One end of the rack is immersed in a container of xylol as illustrated in Fig. 3 to remove from the braid any coating used during the braiding process. The rack is removed from the container and the xylol is permitted to evaporate from the braided silk at room temperature.

That end of the rack that has been treated with xylol is then immersed in a container of a resin solution as described in Example I above.

The rack is removed from the resin solution and air dried at room temperature for a minimum of ½ hour. The sutures are then removed from the rack by cutting along the lines X—X and A—A. The sutures so obtained are approximately 18 inches in length and the resin-coated end measures about ½ to 1 inch. The diameter of the resin-coated end is 12.6 mils (determined optically).

EXAMPLE IV

A Size 0 black braided silk strand characterized by an optically determined diameter of 15.8 mils is wound on a rack 19¼ inches in width under a tension of 2 pounds, using the apparatus illustrated in Fig. 1. One end of the rack is immersed in a container of xylol as illustrated in Fig. 3 to remove from the braid any coating used during the braiding process. The rack is removed from the container and the xylol is permitted to evaporate from the braided silk at room temperature.

That end of the rack that has been treated with xylol is then immersed in a container of a resin solution as described in Example I above.

The rack is removed from the resin solution and air dried at room temperature for a minimum of ½ hour. The sutures are then removed from the rack by cutting along the lines X—X and A—A. The sutures so obtained are approximately 18 inches in length and the resin-coated end measures about ½ to 1 inch. The diameter of the resin-coated end is 15.6 mils (determined optically).

WHAT WE CLAIM IS:—

1. A method of preparing a multifilament suture which comprises winding a strand of suture material onto a rack under tension, dipping a section, intended for eventual cutting, of the wound strand into a supply of binder material while under tension, removing the strand on the rack from the binder supply and air-drying the binder-coated strand before releasing it from the rack.

2. A method according to Claim 1, wherein the binder material is a resin solution.

3. A method according to Claim 2, wherein said resin is a polyester resin or epoxy resin.

4. A method according to any preceding Claim, wherein the suture is of a braided construction.

5. A method according to any preceding Claim, wherein the suture is of a covered construction.

6. A method according to any of Claims 1 to 3, wherein the whole length of the suture is manufactured of cotton or linen.

7. A method according to any of Claims 1 to 3, wherein the whole length of the suture is manufactured of a synthetic copolymer of L(-) lactide and glycolide.

8. A method according to any of Claims 1 to 3, wherein the whole length of the suture is manufactured of a braided polyhydroxyacetic ester.

9. A method according to any of Claims 1 to 3, wherein the whole length of the suture is manufactured of braided silk.

10. A method according to any of Claims 1 to 3, wherein the whole length of the suture is manufactured of braided polyester.

11. A method of preparing a surgical suture substantially as hereinbefore described.

12. A method of preparing a surgical suture substantially as hereinbefore described with reference to the Examples and/or the accompanying drawing.

13. A surgical suture prepared by the method of any preceding Claim.

For the Applicants:
CARPMAELS & RANSFORD,
Chartered Patent Agents,
43 Bloomsbury Square,
London WC1A 2RA.

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1428560 COMPLETE SPECIFICATION
1 SHEET *This drawing is a reproduction of the Original on a reduced scale*

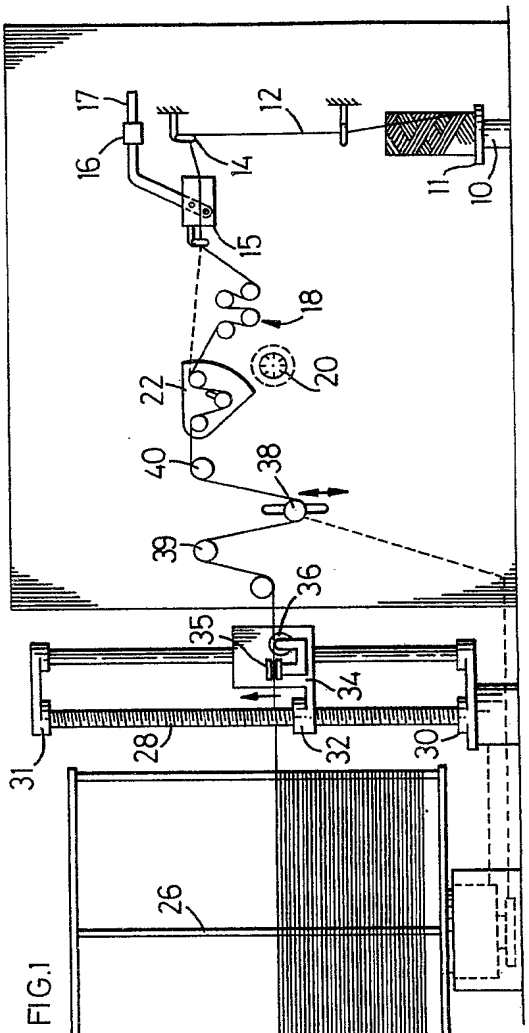

FIG.1

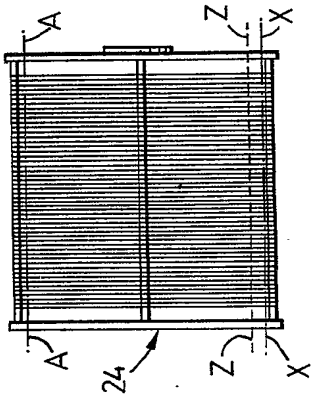

FIG.4

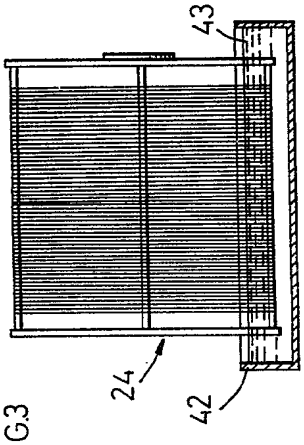

FIG.3

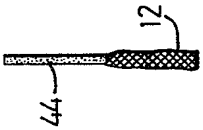

FIG.5

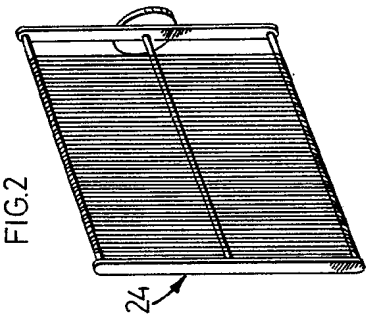

FIG.2